JAN 2 6 2012

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K120075

Submitter

Advanced Instrumentations, Inc.
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Registration # 1066270

Official correspondent :

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Date Prepared:

January 6, 2012

Device name and classification:

- **Device Name:** AM-6000 Anesthesia Machine
- **Classification Name:** 868.5160 System, Gas-Machine, Anesthesia
  Product code: BSZ
- **Regulatory Class:** II

Predicate Device:

AS3000 Navigator Anesthesia Delivery System. K080175 Manufacturer: Datascope Corp.

Device Description:

The AM-6000 Anesthesia Machine is a continuous flow Anesthesia Machine which offers manual or automatic ventilation, easily adjustable fresh gas delivery, anesthetic agent delivery, ventilation monitoring, convenient ergonomics, and state-of-the-art safety systems. The AM-6000 is designed to decrease the risk of hypoxic mixtures and the inadvertent movement of the air flow control knobs. Additionally, the AM-6000 provides battery power in the event of an AC power outage.

Multiple ventilation modes, i.e., CMV, PCV, SIMV and PSV, are offered by the AM-6000 with electronic PEEP available in each of the modes. The fresh gas dosing subsystem offers features of a traditional Anesthesia Machine along with dual flow tubes which display the gas flows at all times. The AM-6000 contains two vaporizers and a heated breathing system to minimize condensation and return moisture to the patient.

Indications for Use:

The AM-6000 Anesthesia machine is intended for general anesthesia use. The AM-6000 Anesthesia machine will delivery operator set concentrations of oxygen and anesthesia gases as well as deliver controlled breaths to the patient with either a constant or a deceleration flow pattern. AM-6000 Anesthesia machine is also intended to allow for the provision of manual ventilation.

Intended operator:

The AM-6000 Anesthesia machine is intended for use by Healthcare professionals who are trained in the administration of anesthesia.

Intended Patient Populations:

The AM-6000 Anesthesia machine is intended for use on the neonatal to adult patient populations in all ventilation modes.

Intended Use Environment:

The AM-6000 Anesthesia machine is intended to be used in the environments where anesthesia is to be administered by Healthcare professionals trained in administering anesthesia.

Effectiveness and Safety Contraindications:

Clinical Test

Clinical testing is not required

Non-clinical test:

The AM-6000 Anesthesia Machine has been tested and found to be in compliance with recognized safety, performance and electromagnetic compatibility standards.

A risk analysis has been developed to identify potential hazards and document the mitigation of the hazards. The device's software has been validated in accordance with the requirements set forth in the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005).

Comparison to the predicate device:

The subject device has similar technology characteristics and has the same intended use, same material components, same manufacturing process, same design principle, same electrical classification, same measurement mode and same accuracy as the predicate device.

Substantially Equivalent Determination:

Verification and validation testing was done on the AM-6000 Anesthesia Machine. This premarket notification submission demonstrates that AM-6000 Anesthesia Machine is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Advanced Instrumentations, Incorporated
C/O Dr. Jorge Millan
Official Correspondent
Hialeah Technology Center, Incorporated
West 20th Street
Hialeah, Florida 33010

JAN 26 2012

Re: K120075
Trade/Device Name: AM-6000 Anesthesia Machine
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ
Dated: January 6, 2012
Received: January 10, 2012

Dear Dr. Millan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

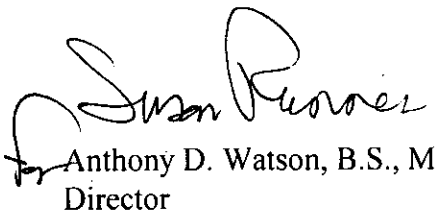
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name:

AM-6000 Anesthesia Machine

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Prescription Use _X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultheiss

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K042007S